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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,238	12/05/2001	Lawrence A. Shimp	525400-208	8543

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EXAMINER	
WILLSE, DAVID H	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 03/24/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/005,238	Applicant(s) SHIMP ET AL.
	Examin r Dave Willse	Art Unit 3738

-- The MAILING DATE of this communication app ars on th cov r sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 08 January 2004.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-138 is/are pending in the application.

4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-10,12-14,18-20,22,23,25-29,33,60-63,72,73,80,86,87,114-116,127 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 12/5/03
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 11,15-17,21,24,30-32,34-59,64-71,74-79,81-85,88-113,117-126 and 128-138.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 114-116 are rejected under 35 U.S.C. 101 because of the positive recitation of the "vertebral load" (claim 114, line 3) and thus the vertebrae of the patient (MPEP 2105, last paragraph); it is recommended that "thereon" be replaced by --direction--.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 7-9, 13, 14, 18, 20, 23, 25, 28, 29, 33, 60-63, and 80 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Anderson et al., US 6,200,347 B1. Regarding claim 1 and others, the slot of the pin (column 28, lines 59-62) defines a pair of spaced apart elongate portions each with a longitudinal axis; upon insertion of the pin, the outer surfaces of said (expanded) portions are inherently under tension, whereas the inner surfaces of said portions, along with other regions of the pin, are under compression. Regarding claim 2: column 28, lines 54-57. Regarding claim 7 and others: column 14, line 1 et seq.

Claims 4-6, 10, 12, 19, 22, 26, 27, 72, 73, 86, 87, 114-116, and 127 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al., US 6,200,347 B1. Regarding claim 4 and others, the longitudinal axes of the pins and the pin sections being substantially along the fiber direction would have been immediately obvious, if not inherent, from the manufacturing procedure discussed at column 17, line 38 et seq., and illustrated in Figure 11B. Regarding claim 5 and others, the claimed fiber direction would have been obvious, if not inherent, from the methods depicted in Figures 11A and 12. Regarding claim 10, an L-shaped abutment would have been obvious in order to simplify the process of forming the interlocking means described at column 14, lines 2-20, especially when such a feature is to be supplemented with locking pins. Regarding claim 12 and others, the threaded pins (e.g., column 5, lines 43-50) likewise inherently possess portions under compression and portions under tension after insertion, and the through-holes being slightly offset from one another would have been obvious in view of the manufacturing tolerances associated with the holes and interlocking means and in view of the stresses to which the implant is subjected. Regarding claim 22 and others, Anderson et al. disclose various pin shapes, and to use a slotted pin in combination with a threaded pin, for

example, would have been obvious in order to better stabilize the assembly against different types of stresses. Regarding claim 116 and others, the surfaces of the through-holes being demineralized would have been obvious, if not inherent, from column 12, lines 6-16. Regarding claim 127: column 19, lines 22-29; column 28, lines 13-14; column 29, line 21; etc.

The Applicant's remarks have been considered. In regard to claim 1 and the Anderson et al. patent, the axes defined by the pair of spaced apart elongate portions are clearly parallel to and offset from one another (and to an axis defined by the slot itself). In response to the Applicant's request that the examiner provide references that teach an inherent tension, attention is directed to the attached copy of page 165 from Wylie et al., *Advanced Engineering Mathematics* (1995). The spaced apart elongate portions of the Anderson et al. slotted pin are deflected from their pre-formed states by the wall of the through-hole (in order for the pin to serve as a connector) and can thus each be represented (at least in part) by a deflected beam of the sort illustrated in Figure 2.6 of Wylie et al. In regard to claim 87 and others, as seen from the attached copy of page 941 from Guyton, *Textbook of Medical Physiology*, 7th edition (1986), the structure of bone includes collagen fibers extending along lines of tensional force and crystalline salts deposited in the organic matrix of bone. Anderson et al. discloses cutting along the length of a cortical bone shaft **61** (Figure 11A; column 17, lines 11-37) and along a cross-section of a femur (Figure 12; column 18, lines 7-25) so as to obtain various geometries and (inherent) fiber orientations.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse whose telephone number is (703) 308-2903. The examiner can normally be reached Monday through Thursday and often on Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Dave Willse
Primary Examiner
Art Unit 3738

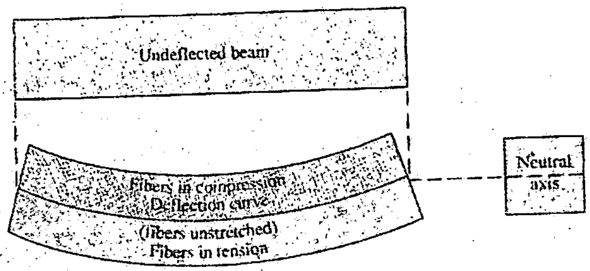


Figure 2.6
A beam before and after bending.

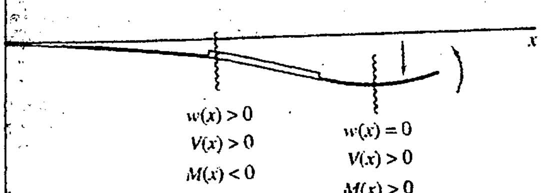
Another important field in which linear differential equations often arise is the bending of beams. Consider a beam which in its undeflected position extends in the direction of the positive x axis. When the beam is bent, it is obvious that the fibers near the concave surface of the beam are compressed, whereas those near the convex surface are stretched. Somewhere between these regions of compression and tension there must, from considerations of continuity, be a surface whose fibers are neither compressed nor stretched. This is known as the **neutral surface** of the beam, and the curve of any particular fiber in this surface is known as the **elastic curve,** or **deflection curve,** of the beam and is taken as the idealized beam itself. The line in which the neutral surface is cut by any plane cross section of the beam is known as the **neutral axis** *of that cross section* (Fig. 2.6).

The loads which cause a beam to bend may be of two sorts: they may be continuously distributed with a density $w(x)$ known as the **load per unit length,** or they may be concentrated at one or more points along the beam. A concentrated load is of course a mathematical fiction which cannot be realized physically since any nonzero load concentrated at a single point would imply a force of infinite intensity which would immediately cut through the beam. Nonetheless, the use of concentrated loads in analyzing various physical systems, such as beams and strings, is both common and fruitful.

A **transverse force** is one whose direction is perpendicular to the length of the beam. The **shear** $V(x)$ at a point x along the beam is the resultant, or algebraic sum, of all transverse forces which act on the beam on the positive side of x. The **moment** $M(x)$ at x is defined as the total moment produced at x by all forces, transverse or not, which act along the beam on one side, or else the other, of the point in question. We shall consider transverse loads and shearing forces to be positive if they act in the direction of the negative y axis (the direction in which loads usually act on a beam). The moment we shall take to be positive if it acts to bend the beam so that it is concave toward the positive y axis (Fig. 2.7). With these conventions of sign (which are not universally adopted), it is shown in the study of the strength of materials that the deflection curve of the beam satisfies the second-order differential equation

$$EIy'' = M \tag{10}$$

Figure 2.7
The conventions for the signs of the moment, shear, and load per unit length at a general point of a beam.



BONE AND ITS RELATIONSHIPS TO EXTRACELLULAR CALCIUM AND PHOSPHATES

Bone is composed of a tough *organic matrix* that is greatly strengthened by deposits of *calcium salts*. Average *compact bone* contains by weight approximately 30 per cent matrix and 70 per cent salts. However, *newly formed bone* may have a considerably higher percentage of matrix in relation to salts.

Th Organic Matrix of Bone. The organic matrix of bone is 90 to 95 per cent *collagen fibers*, and the remainder is a homogeneous medium called *ground substance*. The collagen fibers extend primarily along the lines of tensional force. These fibers give bone its powerful tensile strength.

The ground substance is composed of extracellular fluid plus *proteoglycans*, especially *chondroitin sulfate* and *hyaluronic acid*. The precise function of these is not known, though perhaps they help to control the deposition of calcium salts.

The Bone Salts. The crystalline salts deposited in the organic matrix of bone are composed principally of *calcium* and *phosphate*, and the formula for the major crystalline salts, known as *hydroxyapatites*, is the following:

$$Ca^{++}{}_{10-x}(H_3O^+)_{2X} \cdot (PO_4)_6(OH^-)_2$$

Each crystal—about 400 Å long, 10 to 30 Å thick, and 100 Å wide—is shaped like a long, flat plate. The relative ratio of calcium to phosphorus can vary markedly under different nutritional conditions, the Ca/P ratio on a weight basis varying between 1.3 and 2.0.

Magnesium, sodium, potassium, and *carbonate* ions are also present among the bone salts, though x-ray diffraction studies fail to show definite crystals formed by these. Therefore, they are believed to be conjugated to the hydroxyapatite crystals rather than organized into distinct crystals of their own. This ability of many different types of ions to conjugate to bone crystals extends to many ions normally foreign to bone, such as *strontium, uranium, plutonium, the other transuranic elements, lead, gold, other heavy metals,* and *at least 9 of 14 of the major radioactive products released by explosion of the hydrogen bomb*. Deposition of radioactive substances in the bone can cause prolonged irradiation of the bone tissues, and, if a sufficient amount is deposited, an osteogenic sarcoma (bone cancer) almost invariably eventually develops.

Tensile and Compressional Strength of Bone. Each collagen fiber of *compact* bone is composed of repeating periodic segments every 640 A along its length; hydroxyapatite crystals lie adjacent to each segment of the fiber, bound tightly to it. This intimate bonding prevents "shear" in the bone; that is, it prevents the crystals and collagen fibers from slipping out of place, which is essential in providing strength to the bone. In addition, the segments of adjacent collagen fibers overlap each other, also causing hydroxyapatite crystals to be overlapped like bricks keyed to each other in a brick wall.

The collagen fibers of bone, like those of tendons, have great tensile strength, while the calcium salts, which are similar in physical properties to marble, have great compressional strength. These combined properties, plus the degree of bondage between the collagen fibers and the crystals, provide a bony structure that has both extreme tensile and compressional strength. Thus, bones are constructed in exactly the same way that reinforced concrete is constructed. The steel of reinforced concrete provides the tensile strength, while the cement, sand, and rock provide the compressional strength. Indeed, the compressional strength of bone is greater than that of even the best reinforced concrete, and the tensile strength approaches that of reinforced concrete.

PRECIPITATION AND ABSORPTION OF CALCIUM AND PHOSPHATE IN BONE—EQUILIBRIUM WITH THE EXTRACELLULAR FLUIDS

Supersaturated State of Calcium and Phosphate Ions in the Extracellular Fluids with Respect to Hydroxyapatite. The concentrations of calcium and phosphate ions in extracellular fluid are considerably greater than those required to cause precipitation of hydroxyapatite. However, inhibitors are present in most tissues of the body, as well as in plasma, to prevent such precipitation; one such inhibitor is pyrophosphate. Therefore, hydroxyapatite crystals fail to precipitate in normal tissues except in bone despite the state of supersaturation of the ions.

Mechanism of Bone Calcification. The initial stage in bone production is the secretion of collagen molecules (called collagen monomers) and ground substance by *osteoblasts*. The collagen monomers polymerize rapidly to form collagen fibers, and the resultant tissue becomes *osteoid*, a cartilage-like material but differing from cartilage in that calcium salts precipitate in it. As the osteoid is formed, some of the osteoblasts become entrapped in the osteoid and then are called *osteocytes*.

Within a few days after the osteoid is formed, calcium salts begin to precipitate on the surfaces of the collagen fibers. The precipitates appear at periodic intervals along each collagen fiber, forming minute nidi that rapidly multiply and grow over a period of days and weeks into the finished product, *hydroxyapatite crystals*.

The initial calcium salts to be deposited probably are not hydroxyapatite crystals but, instead, amorphous compounds (noncrystalline), a probable mixture of such salts as $CaHPO_4 \cdot 2H_2O$, $Ca_3(PO_4)_2 \cdot 3H_2O$, and others. Then by a process of